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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS-2015-0005]

Ongoing Equivalence Verifications of Foreign Food Regulatory Systems

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice; response to comments.

SUMMARY: The Food Safety and Inspection Service (FSIS) is responding to comments on the Federal Register notice, "Ongoing Equivalence Verifications of Foreign Food Regulatory Systems," it published on January 25, 2013.

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SUPPLEMENTARY INFORMATION:

#### Background

Imported meat, poultry, and egg products must meet all applicable statutory provisions and regulations, including standards for safety, wholesomeness, and labeling applicable to similar products produced in the United States (see 21 U.S.C 620, 466, and 1046; 9 CFR 327.2, 381.196, and 590.910). Foreign

meat, poultry, and egg products food regulatory systems may apply equivalent sanitary measures if those measures provide the same level of public health protection achieved by U.S. measures.

Any country can apply for eligibility to export meat, poultry, or egg products to the United States. Based on FSIS's review of the information and documentation that the country submits, FSIS decides whether the foreign country's food regulatory system meets all U.S. requirements in the same or an equivalent manner. This is the document analysis. If so, FSIS performs an on-site audit of the entire foreign meat, poultry, or egg products regulatory system. When both the document analysis and on-site audit show that the country's system is equivalent to that of the U.S., FSIS publishes a proposed rule in the Federal Register that announces the results of the first two steps and proposes to add the country to its list of countries eligible to export to the U.S. in FSIS's regulations. After analyzing the public comments that it receives, FSIS makes a final decision about whether the country's system is equivalent based upon all the information it has gathered and publishes a final rule in the Federal Register announcing its determination on the country's eligibility. This comprehensive process is described fully on FSIS's Web site at <http://www.fsis.usda.gov/wps/portal/fsis/topics/international->

[affairs/importing-products/equivalence/equivalence-process-overview](#).

Once a country is determined to be eligible to export to the United States, FSIS continues to monitor that country's food regulatory system. In a notice published in the Federal Register on January 25, 2013, "Ongoing Equivalence Verification of Foreign Food Regulatory Systems," (78 FR 5409) (hereafter "the Federal Register notice"), FSIS described how it conducts ongoing activities to ensure that food regulatory systems of countries that export meat, poultry, or processed egg products to the United States remain equivalent to FSIS's system. FSIS explained that it uses a three-part approach that includes (1) document reviews, (2) on-site system audits, and (3) port-of-entry (POE) reinspections. FSIS determines the scope and frequency of foreign on-site system audits based on its analysis of the results of its document reviews and its ongoing assessment of a country's performance. This performance-based approach allows FSIS to direct its audit resources to foreign food regulatory systems that appear to pose a greater risk to public health than other foreign systems.

FSIS uses the equivalence questionnaire, called the Self-Reporting Tool (SRT), to collect information for FSIS's document review of the food regulatory systems of countries that are listed in the regulations as eligible to export meat, poultry,

or egg products to the United States as well as for the systems of countries interested in becoming eligible (78 FR 5409, January 25, 2013). A copy of the SRT is available on FSIS's Web site at <http://www.fsis.usda.gov/wps/wcm/connect/7893547e-d0d2-4fa9-a984-fdc17228bfcd/SRT.pdf?MOD=AJPERES>. The SRT is a repository for key documents about a foreign food safety inspection system (e.g., inspection system laws, regulations, and policy issuances) that FSIS uses, in addition to on-site audits, to verify whether the laws, regulations, and implementing policies of a foreign country establish an inspection system that is equivalent to the U.S. system. It also allows FSIS to evaluate whether a country maintains system effectiveness and to assess any impacts that an administrative or legislative change has had on a foreign food regulatory system. FSIS conducts a document review at least annually.

The SRT also includes questions for FSIS to use in assessing how frequently it is necessary to conduct on-site audits of the country after FSIS approves export to the United States. FSIS refers to these questions as level of advancement (LOA) questions. The LOA questions are clearly marked in the SRT as "used for scoring purposes." In answering the LOA questions, foreign countries demonstrate the full extent to which they have developed and implemented an equivalent, systems-based approach to food safety regulation that achieves the U.S. level of

protection. The SRT and LOA questions may change over time to reflect changes in the United States' inspection system and associated sanitary measures. As explained in the Federal Register notice, the LOA questions are derived from the Codex Alimentarius Commissions' Guidelines on the Judgment of Equivalence of Sanitary Measures associated with Food Inspection and Certification systems (CAC/GL 53-2003), and the principles outlined in the joint Food and Agricultural Office of the United Nations (FAO) and World Health Organization (WHO) publication, "Assuring Food Safety and Quality: Guidelines for Strengthening National Food Control Systems" (78 FR 5409, January 25, 2013). These questions ask foreign countries to provide information to FSIS on the use of risk analysis principles; the impact of organizational, structural, or administrative change in an exporting country's competent authority; the availability of contingency plans in the country for containing and mitigating the effects of food safety emergencies; the competent authority's willingness and ability to take appropriate actions to manage food safety incidents; and the effectiveness of foodborne disease surveillance systems. For each LOA question, FSIS assigns a score.

In February 2013, FSIS posted more information on LOA questions and scoring in the supplementary document "Performance-Based Approach to Foreign Country Equivalence

Verification Audits and Point-of-Entry (POE) Reinspections,” which is available on FSIS’s Web site at [http://www.fsis.usda.gov/wps/wcm/connect/c10d362b-c978-4578-8b9e-93f956601ccf/Performance Based Approach Equivalence Verification 0213.pdf?MOD=AJPERES](http://www.fsis.usda.gov/wps/wcm/connect/c10d362b-c978-4578-8b9e-93f956601ccf/Performance_Based_Approach_Equivalence_Verification_0213.pdf?MOD=AJPERES). In the Federal Register notice and the supplementary document, FSIS provided examples of criteria applied to assign an LOA to two aspects of a foreign country’s regulatory system (i.e., risk analysis and POE results) but did not provide details on how the various assignments were combined to determine a foreign food regulatory system’s overall LOA (78 FR 5409, January 25, 2013). FSIS has since updated and streamlined the SRT questions and restructured the LOA questions (80 FR 9428, February 23, 2015). As a result, FSIS has changed the way that it scores LOA questions. Specifically, a score of zero or one is assigned for each LOA question. FSIS summarizes these scores and applies adjustments as needed to ensure meaningful comparisons when setting each country’s LOA. FSIS intends to update the supplementary document to provide more information about this change.

FSIS uses the results from the analysis of the LOA questions, previous on-site audits, and POE results to place exporting countries into one of three categories based on food safety performance, with corresponding audit frequencies: well-

performing countries are to be audited every three years;  
average-performing countries are to be audited every two years;  
and adequately-performing countries are to be audited every  
year.

FSIS received approximately 31 comments in response to the Federal Register notice from foreign countries, trade consulting groups, consumer groups, private citizens, a trade association representing the meat industry, and a member of the U.S. Congress.

#### Recent Changes

On February 23, 2015, FSIS responded to comments on the Agency's document review process for determining and verifying initial and ongoing equivalence (80 FR 9428). FSIS announced that it had streamlined the SRT and launched a Web-based version within its Public Health Information System (PHIS) to more efficiently capture up-to-date information about foreign food regulatory systems.

A summary of the other issues raised by the commenters in response to the Federal Register notice and the Agency's responses are below. In addition, FSIS updated the National Advisory Committee on Meat and Poultry Inspection (NACMPI) and the public on the Agency's progress in incorporating NACMPI's 2008 recommendations on the equivalence process on January 7, 2014, and again on January 13, 2015 (see 78 FR 77643 and 79 FR

77441). On January 7, 2014, FSIS received three comments on the Agency's methodology from two consumer groups and a farmer. On January 13, 2015, FSIS received three comments from two consumer groups and a trade association that represents meat processors. These comments are also summarized and addressed below.

#### Summary of Comments

Comment: Several commenters stated that FSIS should have published the proposed changes to its ongoing equivalence verification process in the Federal Register and considered comments from the public before the Agency implemented any of the changes. The commenters argued that FSIS should not have changed its food safety inspection program without stakeholder involvement. A few commenters stated that FSIS should have also conducted a risk assessment and economic analysis before making any changes to its ongoing equivalence verification process.

Response: FSIS made changes to its ongoing equivalence verification process, such as developing the Microsoft Word and Web-based versions of the SRT, transitioning from an annual on-site audit to less frequent on-site audits based on performance, and launching PHIS to schedule POE sampling over a period of years. These changes did not create new requirements for establishments or foreign countries and, therefore, did not require amendments to the relevant regulations. Matters relating to Agency management are exempt from the notice-and-comment



requirements of the Administrative Procedure Act (APA) (5 U.S.C. §553(a)(2)). Similarly, because FSIS did not propose new requirements for the industry or foreign countries, FSIS did not develop a risk assessment or an economic analysis on the Agency's decision to change its ongoing equivalence verification process. Nonetheless, the Agency made its decision-making process public. As noted in the Federal Register notice, FSIS held a public meeting with NACMPI on the changes it intended to make before it made any changes to its ongoing equivalence verification process (78 FR 5409, January 25, 2013). Membership of NACMPI is drawn from representatives of consumer groups; producers, processors, and marketers from the meat, poultry, and egg product industries; State and local government officials; and academia. Therefore, the Agency provided an opportunity for stakeholder input before it made any changes to its ongoing equivalence verification process.

#### On-site Audits

Comment: FSIS received several comments on the frequency of the Agency's on-site audits of foreign countries' food regulatory systems. A foreign country supported the Agency's determination that annual visits to countries are not necessary when those systems are documented to be performing "well" or in an "average" way. The foreign country stated that visits every two to three years to these countries, given the other

information that is available to FSIS, provide the necessary information for FSIS to determine whether these foreign systems continue to meet the U.S. level of protection.

Several commenters stated that FSIS should, at a minimum, conduct annual audits. These same commenters recommended that the scope and intensity of the annual audits should change, based on risk and the conditions in the country when auditors arrive. For example, these commenters stated that information provided through the SRT should provide information necessary for auditors to focus on particular areas of concern that auditors could adjust as appropriate, given actual conditions once they have arrived. The commenters asserted that this approach would ensure that FSIS was auditing foreign countries on a regular basis but would also allow them to devote finite resources to those areas of greatest concern.

Some commenters who stated that FSIS should audit foreign countries' food regulatory systems at least annually stated that FSIS reduced the number of on-site audits because of budget constraints.

One commenter stated that NACMPI never recommended that the Agency shift from annual on-site audits to periodic on-site audits. The commenter asserted that NACMPI recommended that FSIS continue to audit foreign country's food regulatory systems

annually and consider risk in determining whether more frequent or more focused audits were necessary.

Another commenter stated that FSIS is not conducting on-site audits at a minimum frequency of once every three years for all countries that are exporting meat, poultry, or egg products to the United States.

Two commenters stated that food product recalls of imported products from foreign countries show that food safety issues have emerged since FSIS altered its audit frequency schedule. A few other commenters cited recent safety issues related to products produced in China (e.g., baby formula and jerky dog treats linked to illnesses and deaths of babies and dogs, respectively) to support their claim that food products produced in other countries are not always safe and wholesome. The commenters also stated that they were concerned about the safety of poultry products produced in China.

Response: FSIS did not change its methodology because of budget constraints. FSIS determined, based on NACMPI's recommendations and audits conducted over the years, that annual visits are not necessary for countries with systems performing in an average way or well (see 78 FR 5409, January 25, 2013). If FSIS is annually receiving up-to-date documentation from the foreign country on the state of its food safety system, conducting periodic on-site audits of these countries that are

informed by the documentation that the Agency receives, and reviewing and analyzing FSIS POE results, FSIS is able to determine on an on-going basis whether the countries' food regulatory systems are maintaining equivalence to FSIS's system, or whether additional audits are necessary.

FSIS may adjust the scope and intensity of audits based on risk and the conditions in the country when auditors arrive. In addition, for countries that FSIS has determined to be eligible to export product to the U.S., FSIS develops an audit plan based on prior concerns that FSIS has identified with the country's system, any relevant changes the country has made since the last audit, and recent information that the country has submitted to FSIS concerning its system (such as information submitted through the SRT) (see FSIS Notice 35-14, Ongoing Foreign Equivalence Verification Audits, available at <http://www.fsis.usda.gov/wps/wcm/connect/ac10a0c7-792f-4323-a0c7-15a8d4ee71bd/35-14.pdf?MOD=AJPERES>).

NACMPI did not recommend that the Agency conduct annual on-site audits to verify ongoing equivalence. In 2008, NACMPI recommended that the "length of time between audits can be based more on risk and compliance history in the foreign country,"<sup>1</sup> and

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<sup>1</sup> National Advisory Committee on Meat and Poultry Inspection, "Report of Subcommittee Number 1," Washington, DC (2008). Available at: [http://www.fsis.usda.gov/wps/wcm/connect/c669100d-7282-4ee2-b04c-2a799516a962/NACMPI\\_Subcommittee1\\_082708.pdf?MOD=AJPERES](http://www.fsis.usda.gov/wps/wcm/connect/c669100d-7282-4ee2-b04c-2a799516a962/NACMPI_Subcommittee1_082708.pdf?MOD=AJPERES).

that "a three-tiered system may be appropriate."<sup>2</sup> NACMPI also recommended that the scope and frequency of on-site audits and POE reinspections be adjusted based on the capability of a country to be transparent and to share useful regulatory information and compliance history. Under FSIS's three-part approach, FSIS bases the frequency of on-site audits on the results of FSIS's assessment of the country's performance. FSIS assesses all countries annually. The assessment focuses on each eligible country's overall food safety performance relative to the performance of other eligible countries. The assessment includes a statistical analysis of compliance data from POE reinspections and results from FSIS's previous on-site audits of the country's government offices, establishments, and laboratories. This approach is consistent with NACMPI's recommendation that FSIS adopt a risk-informed and compliance-based approach.

FSIS acknowledges that it has not audited all countries eligible to export at least once every three years. Some time was necessary to work through the mechanics of the transition from an annual on-site audit to less frequent on-site audits based on performance (78 FR 5409, January 25, 2013). Going

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<sup>2</sup>National Advisory Committee on Meat and Poultry Inspection, "Report of Subcommittee Number 2," Washington, DC (2008). Available at: [http://www.fsis.usda.gov/wps/wcm/connect/802e06af-81c1-4fc4-b582-6ccea24d8cba/NACMPI\\_Subcommittee2\\_082708.pdf?MOD=AJPERES](http://www.fsis.usda.gov/wps/wcm/connect/802e06af-81c1-4fc4-b582-6ccea24d8cba/NACMPI_Subcommittee2_082708.pdf?MOD=AJPERES).

forward, FSIS will conduct on-site audits of countries eligible to export product to the U.S. at least once every three years.

Approximately the same number of recalls involving imported products occurred when FSIS conducted annual on-site audits as have occurred since FSIS changed the frequency of on-site audits in certain countries.<sup>3</sup> FSIS is committed to protecting the health of U.S. consumers, and it will continue to make every effort to ensure that meat, poultry, and egg products imported into the United States are as safe as products produced in this country.

Finally, regarding concerns about products from China, FSIS does not inspect baby formula or jerky dog treats. These products are under the jurisdiction of the U.S. Food and Drug Administration (FDA). Currently, China is only authorized to export to the United States processed poultry products that originated in the U.S. or another equivalent country. FSIS will reinspect at POE any processed (fully cooked) poultry products exported from China. China has not yet exported such product to the United States. FSIS will conduct annual on-site audits of China's regulatory system for at least the next three years, as

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<sup>3</sup> From 2004 to 2008, approximately 16 recalls involved imported amenable products. In 2009, FSIS began its transition from its annual on-site audit to less frequent audits based on performance; there were approximately six recalls that year. From 2010 to 2014, there were approximately 15 recalls. FSIS did not include recalls that involved amenable products produced by a foreign establishment that were delivered into commerce without the benefit of FSIS POE reinspection because FSIS has changed its policy on these types of recalls over the years.

the Agency would do for any country that has just been found to be equivalent.

Comment: A few commenters requested that FSIS provide data that show that the new methodology with periodic on-site audits provides the same level of public health protection as FSIS's previous approach with annual on-site audits. The commenters stated that if the data do not exist, then FSIS should establish metrics to measure the effectiveness of the new methodology.

Response: FSIS has had almost 20 years of experience in determining and verifying system equivalence, including conducting on-site audits and POE reinspections. Based on this accumulated experience and on-going analysis discussed in the next paragraph, FSIS is confident that its current approach provides for at least the same level of public health protection as FSIS's previous approach with annual on-site audits. As noted above, approximately the same number of recalls involving imported products occurred when FSIS conducted annual on-site audits as have occurred since FSIS changed the frequency of on-site audits in certain countries.

FSIS measures the effectiveness of its methodology by routinely analyzing information from document reviews, on-site audits, and data from POE reinspections and recalls related to imported products. Since the PHIS import module was implemented on May 29, 2012, FSIS has used PHIS to generate detailed

reports, including reports on the amount of product presented for reinspection; the types of activities performed at reinspection; the amount of product refused entry; and whether the product was refused because it failed a Public Health Critical exam (e.g., positive result for Shiga toxin-producing Escherichia coli (STEC) in raw, non-intact beef product). FSIS uses the reports to track trends and to facilitate routine management oversight. FSIS generates these reports at least quarterly. FSIS's analysis of this reported data shows that FSIS's current approach ensures that imported meat, poultry, or egg products are safe, wholesome, and properly labeled.

Comment: FSIS also received several comments on how the Agency determines a country's performance score. One commenter stated that FSIS should not determine the performance score for each eligible country based on a comparison of one country's performance to another country's performance because it is similar to "curve grading." The commenter stated that the "curve grading" concept could provide a false sense of food safety compliance when countries are being evaluated relative to one another instead of against FSIS's import requirements.

Two commenters stated that it was not clear how frequently FSIS will audit each country. The commenters requested that FSIS identify which countries it will audit on an annual basis.



A few commenters asserted that the LOAs are not well defined and requested that FSIS clarify how it will assign LOAs when determining a country's performance score. One commenter stated that assigning an LOA to each country or to each equivalence component would complicate the process, and that FSIS should assign one LOA to a group of factors.

Response: FSIS disagrees that the Agency's performance assessment could provide a "false sense of food safety compliance." The countries are being evaluated against FSIS's requirements. Further, FSIS will not release the specific annual audit schedule with names of countries it will audit each year because of concerns about security of its auditors, and because providing this information in advance may allow countries too much time to prepare in advance for their audits.

As explained above, the SRT includes LOA questions that FSIS encourages countries to answer to demonstrate what they are doing that is above and beyond what is required to be equivalent to FSIS's system. FSIS then scores the responses.

The LOA responses are just one of the factors that FSIS considers as part of an annual analysis of country performance to determine the frequency and scope of on-site audits (78 FR 5409, January 25, 2013). Previous on-site audits and POE results also contribute to FSIS's assessment of a country's performance

and to FSIS's determination of the appropriate audit frequency for that country.

Comment: A few commenters encouraged FSIS to post its audit reports on its Web site in a timelier manner. One commenter noted that prior to 2009, FSIS posted its audit reports within 120 days of the completion of the audit.

Response: FSIS intends to make audit reports public in a timelier manner. FSIS is currently evaluating how best to improve and streamline this process.

#### POE reinspections

Comment: One commenter stated that the frequency of POE reinspection testing for microbiological and chemical hazards should be dependent on the outcomes of country performance. The commenter previously received regular updates from FSIS on consignment testing frequency and results of testing for a particular country, with a breakdown by species and defect type. The commenter requested that FSIS resume this reporting and questioned whether it can be provided to exporting countries through PHIS.

Another commenter stated that FSIS should offer more incentives to high performing countries in addition to reduced audit frequency. The commenter argued that FSIS should not reinspect every product from high performing countries. A few other commenters stated that FSIS should streamline the

reinspection process by allowing the exporting countries to conduct inspections and sampling prior to shipment. The commenters asserted that this process would provide for the earliest possible detection of potential problems, prevent recalls, and reduce considerable transport and subsequent storage costs associated with such shipments. Another commenter suggested that FSIS collaborate with the FDA and U.S. Customs and Border Protection (CBP) to develop a consistent standard in the U.S. for determining which products are low or high risk.

Response: FSIS is working to develop reports on POE testing for exporting countries. These reports will be provided through PHIS. FSIS will notify exporting countries when these reports are available.

FSIS does not intend to change its POE reinspection procedures at this time. In compliance with statutory and regulatory requirements (21 U.S.C. 620, 466, and 1046; 9 CFR 327.6, 381.199, and 590.925), FSIS reinspects all shipments presented at ports of entry to ensure proper certification by the foreign country and examines each shipment for general condition and labeling compliance. Additionally, PHIS randomly assigns more targeted reinspections of the meat and poultry presented to include laboratory sampling and testing to identify microbiological pathogens, drug and chemical residues, and species. PHIS assigns the type of reinspection based on

compliance history of the foreign establishment and country and product volume.

Because FSIS reinspection is necessary to ensure that all imported meat, poultry, and egg products are properly labeled and not adulterated, FSIS will not rely on other country results in determining whether to allow the product to enter domestic commerce. However, FSIS is committed to collaborating with other U.S. agencies to enhance and streamline inspection efforts. For example, in April 2014, FSIS began a pilot program with CBP's Participating Government Agency (PGA) Message Set, which allows FSIS to electronically collect the information required by FSIS form 9540-1, Import Inspection Application and Report (see 79 FR 56220). FSIS's PHIS interfaces with CBP's Automated Commercial Environment (ACE), enabling a seamless transfer of data required for the application for FSIS import inspection in advance of the shipment arrival. The PGA Message Set pilot will remove tens of thousands of paper-based entry forms from the process and will save Agency resources by avoiding manual data entry. Meat, poultry, and processed egg product inspection and enforcement will be more efficient by having the required data available when shipments arrive at the official import inspection facility, benefitting FSIS, industry, trading partners, and U.S. citizens.

In addition, the PGA Message Set pilot supports more efficient protection of public health by transferring all data from the industry for products under FSIS jurisdiction, thus providing the Agency with specific information on FSIS regulated products that could be potentially entering the country from ineligible sources.

Finally, the pilot will facilitate compliance through early filing. Through ACE, importers file their FSIS application with their Customs entry, in advance of the shipment arriving at the official import inspection establishment. This early filing will enable FSIS inspection personnel to better monitor shipments and will facilitate faster recalls if amenable products produced by foreign establishments are delivered into commerce without the benefit of FSIS POE reinspection.

#### USDA Non-Discrimination Statement

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#### How to File a Complaint of Discrimination

To file a complaint of discrimination, complete the USDA Program Discrimination Complaint Form, which may be accessed online at [http://www.ocio.usda.gov/sites/default/files/docs/2012/Complain\\_combined\\_6\\_8\\_12.pdf](http://www.ocio.usda.gov/sites/default/files/docs/2012/Complain_combined_6_8_12.pdf), or write a letter signed by you or your authorized representative.

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Persons with disabilities who require alternative means for communication (Braille, large print, audiotape, etc.), should contact USDA's TARGET Center at (202) 720-2600 (voice and TDD).

#### Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this Federal Register publication on-line through the FSIS Web page located at: <http://www.fsis.usda.gov/federal-register>.

FSIS also will make copies of this publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, Federal Register notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The Update is available on the FSIS Web page. Through the Web page, FSIS is able to provide information to a much broader, more diverse audience. In addition, FSIS offers an email subscription service which provides automatic and customized access to selected food safety news and information. This service is available at: <http://www.fsis.usda.gov/subscribe>. Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

Done in Washington, DC on: May 5, 2015.

Alfred V. Almanza

Acting Administrator.

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